Docket No.: 140942001311
Client Docket No.: DX0670KB1B
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gosse J. ADEMA et al.

Application No.: 10/777,524

Filed: February 11, 2004

For: FDF03 POLYPEPTIDE (AS AMENDED)

Confirmation No.: 8025

Art Unit: 1647

Examiner: B. E. Bunner

DECLARATION OF LEWIS LANIER, PH.D.
PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Lewis Lanier, declare as follows:

1. I am an expert in the field of immunology, particularly regarding the molecular and cellular biology of discrete hematopoietic cell populations involved in immune responses. I am currently a Professor in the department of Microbiology and Immunology at the University of California at San Francisco and am a consultant for Schering-Plough BioPharma (formerly DNAX). A copy of my curriculum vitae is attached. I am familiar with the contents of the above-referenced patent application.

2. It is my understanding that the pending claims stand rejected because one of ordinary skill in the art would not find an immediate, well-defined, real world use for FDF03 based on the disclosure of the instant specification.

3. The specification discloses that FDF03 is an Ig receptor superfamily member, and its expression is restricted to cells of the myelomonocytic lineage. *See* the specification at page 42, lines 27-31; page 54, lines 18-22 and page 87, line 35 to page 88, line 6. The specification goes on

to identify a specific role for FDF03 as a regulator of hematopoietic cells including those involved in antigen presentation (*e.g.*, monocytes and dendritic cells). *See id.* at page 68, line 35 to page 69, line 3.

4. The specification's description of FDF03 provides an immediate, well-defined, real world use for the protein as a discrete marker for monocytes, macrophages, and other cells of the myelomonocytic lineage. As described in the specification, FDF03 can be used to detect an increase in number of monocytes in a tissue or lymph system and thus indicate the presence of monocyte hyperplasia, tissue or graft rejection, inflammation or an abnormal response to a bacterial or viral infection. *See id.* at page 87, line 35 to page 88, line 6. The selective expression of FDF03 has been confirmed in work described in a peer-reviewed scientific publication. *See* Fournier, et al., *J. Immunol.* 165(3):1197-1209 (2000). As it is selectively expressed on a discrete subpopulation of cells (*i.e.*, the myelomonocytic lineage), the FDF03 protein accurately and immediately serves as a marker for a discrete cell population and is useful in assessing the relative levels of monocytes. Even without identification of a precise function of this protein or an association with a particular disease state, the expression profile disclosed in the specification provides an instant, real world use for the FDF03 protein.

5. The specification's description of FDF03 provides an immediate, well-defined, real world use for the protein as a regulator of antigen presentation in cells of the myelomonocytic lineage. The specification describes the FDF03 protein as one that "likely plays a role in regulation or development of hematopoietic cells, ... *e.g.*, antigen presentation and the resulting effector functions." *See* the specification at page 68, line 37 to page 69, line 3. It is well known that cells of the myelomonocytic lineage participate in antigen presentation. Assays to assess antigen presentation capacity are well known, readily available, and easily performed by one of ordinary skill in the art. Given the restricted expression of the FDF03 protein, its identity as a Ig receptor family member, and its described role in antigen presentation regulation in the instant application, a person of ordinary skill in the art would appreciate the immediate usefulness of the FDF03 protein. The specific usefulness of the FDF03 protein comes from its identity as a regulator of antigen presentation. Whether it positively or negatively regulates antigen presentation and under what

conditions that regulation occurs is certainly interesting, but it is not necessary for the specific and immediate recognition by one of ordinary skill in the art that the FDF03 protein is useful. In other words, regardless of whether FDF03 is a positive or negative regulator of antigen presentation, it is useful as a modulator of this critical aspect of the immune response.

6. Taken together, it is my opinion that the description in the specification provides more than one immediate, well-defined real world use of FDF03 protein as, for example, a discrete marker for cells of the myelomonocytic lineage and as a regulator of antigen presentation in these cells. Therefore, I believe that the description the instant specification discloses these uses in a manner sufficient for one of ordinary skill in the art to appreciate and immediately exploit these uses in a real word context.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Executed at San Francisco, CA on ___October 8, 2007_____.

Lewis L. Lanier, Ph.D.

Curriculum Vitae

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Citizenship: U.S.A.

Education:

Ph.D. Microbiology and Immunology, University of North Carolina -Chapel Hill, 1978

B.S. Biology (Microbiology), graduated with High Honors, Virginia Polytechnic Institute and State University, 1975

Special Awards and Honors:

President, American Association of Immunologists, 2006-2007

National Institutes of Health MERIT Grant Award, 2006

Keystone Symposia – Lymphocyte Activation and Signaling, Keynote Address, 2006

American Society for Histocompatibility & Immunogenetics Rose Payne Award, 2005

American Association of Immunologist Distinguished Lecture, 2004

American Cancer Society Research Professorship, 2003

William B Coley Award for Distinguished Research in Basic and Tumor Immunology, Cancer Research Institute, New York, 2002

American Association of Immunologists Distinguished Service Award, 2001

Damon Runyon - Walter Winchell Cancer Fund Postdoctoral Fellowship, 1979-1981

National Research Service Award Fellowship, Cancer Research Center, The University of North Carolina School of Medicine at Chapel Hill, 1978-1979

Virginia Polytechnic Institute and State University Freshman Science Scholarship, 1971

Professional Activities:

President, American Association of Immunologists, 2006-2007

Councilor, American Association of Immunologists, 2001-2008

Chairman and Board Member, United States – NIH- Japan Cooperative Medical Science Program Immunology Board, Board Member – 2004; Chairman, 2005 – 2007

Chairman, National Institutes of Health Center for Scientific Review Special Emphasis Panel, 2001, 2003, 2005, 2006

Member, NIH Special Emphasis Panel, NIAID, Biodefense and Emerging Infectious Diseases Research Opportunities, 2004

Member, National Institutes of Health Center for Scientific Review Immunology, Study Section Boundaries Team, 2002

Chairman and Member, National Institutes of Health Experimental Immunology Study Section, 1994-1999. Chairman, 1997-1999

Member, National Institutes of Health Reviewers Reserve, 1989-1993

Member, Cancer Research Institute, CRI Investigator Award Review Committee, 2003-present

Block Chairman, Program Committee, American Association of Immunologists, 1992-1996

Chairman, Program Committee, American Association of Immunologists, 1997-2000

Program Committee, American Society for Histocompatibility and Immunogenetics, 2001

Nominating Committee, American Association of Immunologists, 1994

Council Member, MidWinter Conference of Immunologists, 1992-1997; 1999-2004

Reviews Editor, *Immunity*, 2002-2004

Editorial Board, *Immunity*, 2001-present

Editorial Committee Member, *Annual Review of Immunology*, 2004-2008

Advisory Editor, *Journal of Experimental Medicine*, 1995-2008

Associate Editor, *Journal of Immunology*, 1986-1991

Transmitting Editor, *International Immunology*, 1988-1997, 2001-2005

Editorial Board, *Immunological Reviews,* 2002-present

Editorial Board, *Clinical Immunology and Immunopathology*, 1989-1995

Editorial Board, *Journal of Clinical Immunology*, 1992-1997

Editorial Board, *Tissue Antigens*, 1990-present

Editorial Board, *Human Immunology*, 1999-present

Editorial Board, *Cellular Immunology,* 2000-2004

Editorial Board, *Cancer Immunology Immunotherapy*, 2005-present

Scientific Advisory Board, Protein Design Labs, 2005-present

Scientific Review Board, Schering Plough Biopharma, 2000-present

Board of Directors, Symphony-Dynamo, 2006-present

Scientific Advisory Board, Entelos, Inc., 2000-present

Scientific Advisory Board, Shanghai Genomics, 2005- present

Scientific Advisory Board, Ginkgo Biomedical Research Institute, 2005-present

Scientific Advisory Board, Avipep, 2005-present

Member, Scientific Advisory Council, Cancer Research Institute, 2006-present

Scientific Advisory Board, Institute Pasteur, Department of Immunology, 2004-present

Scientific Advisory Board, International Histocompatibility Working Group, 1999-present

Damon Runyon – Walter Winchell Cancer Research Fund, Alumni Network, 2000-present

Advisory Committee, XIII International Congress on Histocompatibility and Immunogenetics, 2001-2002

Co-organizer, 33rd MidWinter Conference of Immunologists, Asilomar, CA, 1994

Co-organizer, 40th MidWinter Conference of Immunologists, Asilomar, CA 2000

Co-organizer, Keystone Symposium, Molecular and Cellular Biology of Leukocyte Regulatory Receptors, Lake Tahoe, CA 2002

Co-organizer, Keystone Symposium, NK and NKT Cell Biology, 2008

Faculty, FEBS International Summer School on Immunology, Ionian Village, Greece, 1998, 2000, 2002

Faculty, American Association of Immunologists Advanced Course in Immunology, 2000 - 2006

Experience:

Vice Chair, Department of Microbiology and Immunology, University of California San Francisco, 2003-present

Professor, Department of Microbiology and Immunology and the Cancer Research Institute, University of California San Francisco, 1999-present

Director, Department of Immunobiology, DNAX Research Institute for Molecular and Cellular Biology, 1997-1999

Associate Director, Department of Human Immunology, DNAX Research Institute for Molecular and Cellular Biology, 1993-1996

Senior Scientist, Department of Immunology, DNAX Research Institute for Molecular and Cellular Biology, Inc., 1991-1993

Becton Dickinson Research Fellow and Associate Research Director, Becton Dickinson Immunocytometry Systems, 1990-1991

Associate Research Director, Becton Dickinson Immunocytometry Systems, 1988-1991

Senior Research Scientist, Becton Dickinson Monoclonal Center, Inc., 1981-1988

Research Assistant Professor, Department of Pathology, University of New Mexico School of Medicine, 1981

Postdoctoral Fellow, supported by Damon Runyon-Walter Winchell Cancer Fund, University of New Mexico School of Medicine, Department of Pathology, 1979-1981

Postdoctoral Fellow, supported by NIH Training Grant, University of North Carolina Cancer Research Center at Chapel Hill, 1978-1979

University Teaching:

Microbiology 121 (UCSF) – Immunology for Pharmacists (Course organizer 2001)

Microbiology 208 (UCSF) – The Biology of Animal Viruses

Microbiology 204 (UCSF) – Advanced Graduate Immunology

Oral Biology 224 (UCSF) – Immunology for Dentistry Graduate Students

MI 206 (Stanford) - Animal Viruses - Principles of Virus Infection and Pathogenesis

MI212 (Stanford) – Advanced Immunology II

University Service:

UCSF Immunology Program, 1999- present

UCSF Immunology Program, Steering Committee, 2003-2006; Head 2006-

UCSF Biomedical Sciences, graduate training program, Member, 1999-present; Executive Committee, 2005-present

UCSF Program in Biological Sciences, graduate training program, Member, 1999-present; Executive Committee, 2005-present

UCSF Diabetes Center, Member, 2002-present

UCSF Liver Center, Member, 2002-present

UCSF Molecular Medicine Program, Member, 2002-present

UCSF Department of Microbiology & Immunology, Faculty Search Committee, Member, 2000

UCSF Department of Pathology, Faculty Search Committee, Member, 2000-2001

UCSF Sandler Chair of Asthma and Allergy Chair Search Committee, Member, 2000-2002

UCSF Cancer Research Center, Tumor Immunology Faculty Search Committee, Chair, 2001-2002

UCSF Cancer Center, Cancer & Immunity Program, Program Leader, 2000-present

UCSF Cancer Center, Hematological Malignancies Program, Member, 1999-present

UCSF Cancer Research Institute, Merit and Promotions Committee, Member, 2000-2005

UCSF Stewart Trust Cancer Research Award Review Committee, Member, 2001; Co-chair 2002

UCSF American Cancer Society Internal Grant Review Committee, Member, 2002; Chair, 2003-2005

UCSF Diabetes Center Faculty Search Committee, Member, 2002-2005

UCSF Department of Experimental Medicine, Faculty Search Committee, 2006-2007

Gladstone Institute, Faculty Search Committee, Member 2006-2007

Publications:

1. Lanier, L.L., M. Lynes, G. Haughton and P.J. Wettstein. 1978. Novel type of murine B cell lymphoma. Nature 271:554-555.

2. Babcock, G.F., L.L. Lanier, M.A. Lynes and G. Haughton. 1978. A simple method for the preparation of antisera specific for murine immunoglobulin heavy chains. J. Immunol. Methods 23:1-6.

3. Lynes, M.A., L.L. Lanier, G.F. Babcock and G. Haughton. 1978. Antigen-induced murine B cell lymphomas. I. Induction and characterization of CH1 and CH2. J. Immunol. 121:2352-2357.

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5. Haughton, G., L.L. Lanier and G.F. Babcock. 1978. The murine kappa chain shift. Nature 275: 154-157.

6. Lanier, L.L. and G. Haughton. 1979. Tolerance to non H-2 histocompatibility antigens: Transplantation tolerance to the H-4 and H-7 histocompatibility antigens. Transplantation 27:208-211.

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10. Lanier, L.L. and N. L. Warner. 1981. Cell cycle related heterogeneity of Ia antigen expression on a murine B lymphoma cell line: Analysis by flow cytometry. J. Immunol. 126:626-631.

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12. Haughton, G., L.W. Arnold, L.L. Lanier, R.B. Raybourne and N.L. Warner. 1981. Induction of B cell lymphomas in B10.H-2^{a}H-4^{b}p/Wts mice. In: B lymphocytes in the immune response: Functional, developmental and interactive properties. Developments in Immunology, Vol. 15. Eds. N. Klinman, D. Mosier. I. Scher and E. Vitetta, Elsevier North Holland, New York, p. 455-458.

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14. Lanier, L.L. and N.L. Warner, J.A. Ledbetter and L.A. Herzenberg. 1981. Quantitative immunofluorescent analysis of surface phenotypes of murine B cell lymphomas and plasmacytomas with monoclonal antibodies. J. Immunol. 127:1691-1697.

15. Lanier, L.L. and N.L. Warner. 1981. Paraformaldehyde fixation of hematopoietic cells for quantitative flow cytometry (FACS) analysis. J. Immunol. Methods 47:25-30.

16. Warner, N.L., R.K. Cheney, L.L. Lanier, M.J. Daley and E. B. Walker. 1982. Differentiation heterogeneity in murine hematopoietic tumors. In: Maturation factors and cancer. Prog. Cancer Res. Therapy, Vol. 23. Ed. M.A.S. Moore, Raven Press, New York, p. 223-243.

17. Lanier, L.L., G.A. Gutman, D.E. Lewis, S.T. Griswold and N.L. Warner. 1982. Monoclonal antibodies against rat immunoglobulin kappa chains. Hybridoma 1:125-131.

18. Walker, E.B., L.L. Lanier and N.L. Warner. 1982. Characterization and functional properties of B lymphoma and macrophage tumor cell lines in accessory cell replacement assays. J. Immunol. 128:852-859.

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21. Lanier, L.L. and N.L. Warner. 1982. Activation of murine B lymphomas. In: B and T cell tumors. UCLA Symposium of Molecular and Cellular Biology, Vol. 24. Ed. E. Vitetta. Academic Press, New York, p. 431-443.

22. Lanier, L.L., E.B. Walker, E.R. Richie and N.L. Warner. 1982. Murine hematopoietic cell tumors: Models for analysis of cellular differentiation. In: B and T cell tumors. UCLA Symposium on Molecular and Cellular Biology, Vol. 24. Ed. E .S. Vitetta, Academic Press, New York, p.29-42.

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42. Lanier, L.L., J.H. Phillips and N.L. Warner. 1986. Monoclonal antibodies to human lymphocytes. In: Methods in Haematology, Ed. P. Beverley, Chapter 9.

43. Allison, J.P., B.W. McIntyre, F.C-Y. Cheung and L.L. Lanier. 1984. Molecular characterization of the murine T cell antigen receptor In: Regulation of the Immune Response, Eds. H. Cantor, L. Chess and E. Sercarz, Alan R. Liss, Inc., NY, p.389-398.

44. Hogarth, P.M., I.F.C. McKenzie, L. Lanier, D.W. Bailey and B.A. Taylor. 1984. Location of Ly-7 on mouse chromosome 12. Immunogenetics 19:539-543.

45. Lanier, L.L., C.J. Benike, J.H. Phillips and E.G. Engleman. 1985. Recombinant interleukin-2 enhanced natural killer cell-mediated cytotoxicity in human lymphocyte subpopulations expressing the Leu 7 and Leu 11 antigens. J. Immunol. 134:794-801.

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47. Lanier, L.L. and J.H. Phillips. 1986. A map of the cell surface antigens expressed on resting and activated human natural killer cells. In: Leukocyte Typing II, Eds. E.L. Reinherz, B.F. Haynes, L.M. Nadler and I.D. Bernstein, Springer-Verlag, New York, p. 157-170.

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49. Allison, J.P., B.W. McIntyre, L.L. Ridge, J. Gross-Pelose and L.L. Lanier. 1985. Molecular characterization of the murine T cell antigen receptor and associated structures. Federation Proc. 44:2870-2873.

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54. Phillips, J.H. and L.L. Lanier. 1985. A model for the differentiation of human natural killer cells: Studies on the in vitro activation of Leu 11^+ granular lymphocytes with a NK-sensitive tumor cell, K562. J. Exp. Med. 161:1464-1482.

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Research Support - Current

ACTIVE

Grant Number: R37 AI066897 PI: Lewis L. Lanier
Dates of Project: 03/01/06-02/28/11 Granting Agency: NIH NIAID
Title: NK and T Cell Costimulation by NKG2D/DAP10
Amount: $250,000 Annual Direct Costs
The objective of this grant is to study the structural and signaling properties of the NKG2D - DAP10 receptor complex on T cells and NK cells and to study the biological function of this receptor in gene-deficient mice. Lewis Lanier is PI of the grant and responsible for all aspects of the program.

Grant Number: R01AI068129 PI: Lewis L. Lanier
Dates of Project: 02/15/06-01/31/11 Granting Agency: NIH NIAID
Title: NK Cell Receptors and Their Ligands
Amount: $250,000 Annual Direct Costs
The objective of this grant is to study the structure and biological role of receptors on NK cells that associate with the ITAM-bearing adapter molecules DAP12, FcεRIγ, and ζ. Lewis Lanier is PI of the grant and responsible for all aspects of the program.

Grant Number: R01 CA095137 PI: Lewis L. Lanier
Dates of Project: 02/14/03-01/31/08 Granting Agency: NIH NCI
Title: RAE-1 family of proteins in innate and adaptive immunity
Amount: $200,250 Annual Direct Costs
The objective of this grant is to study the role of the RAE-1 family of proteins in anti-microbial immunity, mediated by NK cells, CTL and activated macrophages. Lewis Lanier is the PI of the grant and responsible for all aspects of the program.

Grant Number: P30 CA82103 (McCormick, F.)
Date of Project: 8/5/99- 5/31/12 Granting Agency: NIH NCI
Title: Cancer Center Support Grant
The Cancer Center Support Grant provides support for administration and infrastructure for the UCSF Comprehensive Cancer Center. Dr. Lanier is the Program Leader of the Cancer & Immunity Program.

Grant Number: RP-03-054-01 PI: Lewis L. Lanier
Dates of Project: 01/01/03 – 12/31/07 Granting Agency: American Cancer Society
Title: American Cancer Society Research Professorship
Amount: $80,000 Annual Direct Costs
This is a senior professorship grant awarded to outstanding cancer researchers.

Grant Number: U01-CA105379 PI: Doug Hanahan (Co-PI: Lewis L. Lanier)
Dates of Project: 09/15/04-03/31/09 Granting Agency: NIH/NCI
Title: Immune Enhancement and Therapy of Cancer

Amount: $75,000 Annual Direct Costs
This is an exploratory U01 grant to investigate the role of NK cells in mouse models of primary tumorigenesis.

Grant Number: P01AI64520
PI: Frances Brodsky (Lewis L. Lanier, Project Leader)
Dates of Project: 9/18/05-2/28/10 Granting Agency: NIH/NIAID
Title: Human Natural Killer Cell Biology
Amount: $200,000/Annual Direct Costs
The objective of this grant is to understand recognition and function of human NK cells. Lewis Lanier is the Project Leader of Unit I and will be responsible for all aspects of this Unit, and for interacting with the PI and other Program Leaders in the P01. Dr. Lanier will devote 10% effort towards this grant, which will be sufficient to ensure completion of the scientific aims and administrative oversight of the Project.

Research Support - Completed

Grant Number: R01 AI52127 PI: Chris Goodnow (Co-PI: Lewis L. Lanier)
10%
Dates of Project: 09/15/01 – 6/30/07 Granting Agency: NIH NIAID
Title: Genes for Tolerance and Immunity Consortium
Amount: $387,849 Annual Direct Costs
The objective of this grant is to generate and characterize mutant mice demonstrating defects in the immune system, which will provide models for human disease. This grant is a collaborative effort between Dr. Chris Goodnow (PI) of the Australian National University and Drs. Lewis Lanier, Art Weiss, and Jason Cyster (Co-PI). Dr. Lanier will direct the studies of mice with selective defects in NK cells and CTLs.